

REMARKS

In the outstanding Office Action, Claims 1, 3, 5-12, 15-18, 20, 22-30, 32, 34, 36, and 39 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Number 5,978,709 to Begemann et al. in view of U.S. Patent Number 5,951,593 to Lu et al. Claims 13 and 14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Begemann et al. in view of Lu et al. and further in view of U.S. Patent Number 5,253,644 to Elmvist. Reconsideration is respectfully requested in light of the following remarks.

Applicants' claimed invention, as set forth in independent claims 1, 17, 18, 30, and 36, is directed to a system and corresponding method that paces the heart at an overdrive pacing rate. The claimed system includes a detection unit that monitors for intrinsic heart beats during overdrive pacing. The system further includes an overdrive pacing rate increment unit that increases the overdrive pacing rate if at least two intrinsic beats are detected during a predefined period between about 8 and about 40 cycles.

Thus, the claimed system and method begins overdrive pacing the heart, and if at least two intrinsic beats are detected within an interval between about 8 and about 40 beats, then the overdrive pacing rate is increased. In this manner, the claimed system and method provide a dynamic system that adjusts during overdrive pacing based on detection of at least two intrinsic beats within the relatively long period.

In contrast, the Begemann et al. reference discloses a system and method for overdrive pacing that increases the overdrive pacing rate based on either 1) a single intrinsic event, or 2) 2-3 consecutive atrial senses (Col. 8, lines 50-54). Nowhere do Begemann et al. teach or in any way suggest a system that sets a period of between about 8 and about 40 cycles, and that looks for at least two beats within that period. Rather, Begemann et al. disclose systems that are either too sensitive (increasing the overdrive rate based on a single intrinsic event), or that only respond after the patient is likely already in fibrillation (based on 2-3 c nsecutive intrinsic events). Thus, at most Begemann et al. teach looking for three consecutive atrial senses. But nowhere do

Begemann et al. teach setting a relatively long period between about 8 and about 40 cycles, and of then looking for at least two intrinsic events within that period, where the intrinsic events may be separated by a large number of paced beats.

As described by the Examiner, Lu et al. disclose a system for detecting an onset of atrial fibrillation. When three intrinsic signals over a period of eight cycles are detected, the system detects an atrial fibrillation onset. However, in detecting the three intrinsic signals, Lu et al. looks for ectopic beats that only occur during the total atrial refractory period (TARP) (Col. 6, lines 44-47). "The first counter 110 is enabled only during the total atrial refractory period (TARP) and is designed to count the number of atrial sense signals that occur during this critical period." (emphasis added). Thus, rather than counting all intrinsic atrial events, Lu et al. look only for ectopic events occurring during TARP. Thus, Lu et al. do not teach or in any way suggest a system that detects all intrinsic atrial events, but rather only those associated with atrial fibrillation (i.e., those intrinsic events that occur from ectopic foci rather than from the sinus node). As such, Lu et al.'s '3 of 8' algorithm would not be suitable for overdrive pacing applications, because it would not detect intrinsic rate increases coming from the sinus node.

In addition, there is no suggestion to combine these references together. Begemann et al. are concerned with overdrive pacing, whereas Lu et al. are looking for episodes of atrial fibrillation using their '3 of 8' algorithm. Thus, the two prior art references are concerned with very different problems. Moreover, combining Begemann et al. and Lu et al. would significantly alter the specific teachings of Begemann et al. Begemann et al. specifically looks for consecutive beats, and one would not be motivated by the teachings in Begemann et al. to modify Begemann et al. to look for at least two beats within a predefined period of between about 8 and about 40 cycles. It is well settled that there must be some suggestion to combine references, and that one cannot simply pick and choose from various prior art references to arrive at applicants' claimed invention. "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." ECOLOGCHEM, INC., v. SOUTHERN CALIFORNIA EDISON COMPANY,

227 F.3d 1361 (Fed. Cir. 2000). Applicants respectfully assert that combining Begemann et al. and Lu et al. would amount to hindsight reconstruction, based on the fact that the two references are proposing solutions to two different problems, and in light of Begemann's specific teaching of looking for consecutive beats. Any such combination would materially alter the specific teachings of Begemann et al., and would therefore be nothing more than improper hindsight reconstruction.

Moreover, even if Begemann et al. was modified to use Lu et al.'s '3 of 8' algorithm, one would still not arrive at applicants' claimed invention. As set forth above, Lu et al. only look for ectopic beats during TARP to determine whether the '3 of 8' criteria is satisfied, and specifically ignore intrinsic atrial events that occur outside of TARP. Therefore, even if Lu et al.'s '3 of 8' algorithm were combined with Begemann et al.'s overdrive pacing technique, one would still not arrive at a system in which all intrinsic atrial events, and in particular those occurring from an increasing sinus rate, were detected for purposes of determining whether to adjust the overdrive pacing rate.

Claims 13 and 14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Begemann et al. in view of Lu et al. and further in view of U.S. Patent Number 5,253,644 to Elmvist. As described above, Begemann et al. and Lu et al., taken alone or in combination, fail to teach or suggest Applicants' pending claims. Elmvist is cited solely because it teaches rhythm detection using at least two consecutive P-waves, and Elmvist fails to teach or in any way suggest overdrive pacing. Therefore, combining the teachings of Elmvist with Begemann et al. and Lu et al. still falls short of Applicants' claimed invention.

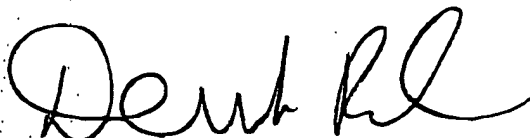
CONCLUSION

In light of the above remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

12/5/03

Date



Derrick Reed, Reg. No. 40,138
Patent Attorney for Applicants

Pacesetter, Inc.
15900 Valley View Court
Sylmar, CA 91392-9221
818/493-2200
818/362-4795 (fax)